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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,383	07/09/2003	Timothy J. Foster	P06335US03/BAS	5842
881 7590 02/26/2008 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			EXAMINER ARCHIE, NINA	
			ART UNIT 1645	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/615,383

Applicant(s)

FOSTER ET AL.

Examiner

NINA A. ARCHIE

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-10 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-10 and 13-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office is responsive to Applicant's amendment and response filed 11-26-07. Claims 2-10 and 13-17 are pending. Claims 2-10, 13, and 15 have been amended. Claims 1 and 11-12 have been cancelled. Claims 16-17 are new claims.

Drawings

2. The drawings in this application have been accepted. No further action by Applicant is required.

Objections/Rejections Withdrawn

3. In view of the Applicant's amendment and remark following objections are withdrawn.

- a) Objection to Oath and Declaration is withdrawn in light of applicant's argument thereto.
- b) Rejection to claims 1-15 under obviousness double patenting rejection is withdrawn in light of applicant cancellation of claims (1 and 11-12), in light of applicant's amendment thereto (claims 2-10, and 13-17), and in light of applicant's filing a terminal disclaimer. The terminal disclaimer filed on 11/26/2007 disclaiming the terminal portion has been reviewed and is accepted. The terminal disclaimer has been recorded.
- c) Rejection of claims 1-5, 8-10, and 11-15 under 35 U.S.C. 102(b) is withdrawn in light of cancellation of the claim 1.

New Grounds of Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 2-5, 7-10, and 11-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Guss et al WO 97/48727.

The claims are drawn to an isolated antibody that binds to the SdrG fibrinogen-binding protein from coagulase-negative *Staphylococcus epidermidis* wherein the SdrG fibrinogen-binding protein is encoded by the nucleic acid comprising SEQ ID NO:7 (claim 7).

Guss et al teach a nucleic molecule and encoded protein from *S. epidermidis* where the protein contains a conserved TYTFTDYVD sequence where the nucleic acid molecule encodes the protein and has about 95% homology to SEQ ID NO: 7 (see Figure 6, and STIC RESULTS). Although Guss does not teach 100% homology to SEQ ID NO: 7, Guss et al inherently teach antibody that binds to an SdrG fibrinogen-binding protein from coagulase-negative *Staphylococcus epidermidis*. Guss et al teach antibodies against the SdrG fibrinogen-binding protein (see pg. 4 last paragraph, Example 1, Example 5). Guss et al teach a diagnostic kit for determining the presence comprising a fibrinogen binding protein originating from coagulase-negative staphylococci (see abstract). Therefore Guss et al anticipate an isolated antibody that binds to the SdrG fibrinogen-binding protein from coagulase-negative *Staphylococcus epidermidis*. Guss et al inherently teach that the protein is cell-wall associated, and binds both soluble and immobilized fibrinogen. Therefore the antibodies of Guss et al recognizes a protein that is cell wall-associated, exhibits cation-dependent ligand-binding and has a highly conserved motif of which the consensus sequence is TYTFTDYVD (SEQ ID NO: 16). Therefore Guss et al anticipate that an isolated antibody is raised against the SdrG fibrinogen-binding protein from coagulase-negative *Staphylococcus epidermidis*, raised against the A region of the SdrG fibrinogen-binding protein from coagulase-negative *Staphylococcus epidermidis*. Guss et al teach that region called A (see Figure 7) of the of the FIG protein (fibrinogen SdrG binding protein) therefore Guss et al anticipate an isolated antibody that is reactive with the ligand binding A region of the SdrG fibrinogen-binding protein from coagulase-negative. Guss et al each isolated antisera containing an antibody (see figure 11). Guss et al teach the consensus sequence is TYTFTDYVD (SEQ ID NO: 16) and antibodies against the protein comprising the sequence thus Guss et al anticipate an isolated antibody reactive with a protein that is cell wall-associated, exhibits cation-dependent ligand-binding and

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has a highly conserved motif of which the consensus is consensus sequence is TYTFTDYVD (SEQ ID NO: 16), wherein the protein is isolated from coagulase-negative Staphylococcus epidermidis (see Figure 6, and STIC RESULTS), wherein the protein comprises SdrG fibrinogen-binding protein isolated from coagulase-negative Staphylococcus epidermidis, wherein the protein comprises the ligand binding A region of SdrG fibrinogen-binding protein isolated from coagulase-negative Staphylococcus epidermidis (see abstract, pg. 4 last paragraph, Example 1, Example 5, Figure 6 and Figure 7).

As to dependent claims 9 and 16-17, a diagnostic kit comprising the antibody; A kit is defined as a set or collection of articles used together therefore Guss et al anticipate a diagnostic kit.

5. Claims 2-10 and 13-17 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,380,370 Doucette-Stamm et al Date April 30, 2002 (US Filing Date August 13, 1998).

The claims are drawn to an isolated antibody that binds to the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis wherein the SdrG fibrinogen-binding protein is encoded by the nucleic acid comprising SEQ ID NO:7 (claim 7).

Doucette-Stamm et al teach an isolated polypeptide and nucleic acid sequences derived from Staphylococcus epidermidis (see SEQ ID NO. 5314) that has 100% homology to the instant SEQ ID NO. 16 and 99.9% to the instant SEQ ID NO. 10. SEQ ID NO: 7 comprises consensus sequence SEQ ID NO: 16, thus Doucette-Stamm et al teach antibodies raised against the polypeptide and nucleic acid of SEQ ID NO: 7 (see abstract, column 3 lines 15-27, column 9 lines 7-27, STIC Results). Thus Doucette-Stamm et al inherently teach antibodies reactive with S. epidermidis polypeptides. Doucette-Stamm et al teach anti-protein/anti-peptide antisera or monoclonal antibodies can be made by standard protocols. Doucette-Stamm et al teach that the progress of immunization can be monitored by detection of antibody titers in plasma or serum (see column 40 lines 29-64). Therefore Doucette-Stamm et al anticipate an isolated antibody

that binds to the SdrG fibrinogen-binding protein from coagulase-negative *Staphylococcus epidermidis*. Doucette-Stamm et al inherently teach the protein is cell-wall associated, and binds both soluble and immobilized fibrinogen. The antibodies of Doucette-Stamm et al inherently recognizes a protein that is cell wall-associated, exhibits cation-dependent ligand-binding and has a highly conserved motif of which the consensus sequence is TYTFTDYVD (SEQ ID NO: 16). Therefore Doucette-Stamm et al anticipate an isolated antibody raised against the SdrG fibrinogen-binding protein from coagulase-negative *Staphylococcus epidermidis*, which is raised against the A region of the SdrG fibrinogen-binding protein from coagulase-negative *Staphylococcus epidermidis*, wherein the SdrG fibrinogen-binding protein comprises SEQ ID NO:10. Doucette-Stamm et al anticipate isolated antisera containing the antibody. Doucette-Stamm et al anticipate an isolated antibody that is reactive with the ligand binding A region of the SdrG fibrinogen-binding protein from coagulase-negative *Staphylococcus epidermidis*. Doucette-Stamm et al anticipate an isolated antibody reactive with a protein that is cell wall- associated, exhibits cation-dependent ligand-binding and has a highly conserved motif of which the consensus sequence is TYTFTDYVD (SEQ ID NO: 16), wherein the protein is isolated from coagulase-negative *Staphylococcus epidermidis*, wherein the protein comprises the SdrG fibrinogen-binding protein isolated from coagulase- negative *Staphylococcus epidermidis*, wherein the protein comprises the ligand binding A region of the SdrG fibrinogen-binding protein isolated from coagulase-negative *Staphylococcus epidermidis* (see abstract, column 3 lines 15-27, column 9 lines 7-27, STIC Results, column 40 lines 29-64).

As to dependent claims 9 and 16-17, a diagnostic kit comprising the antibody and means for identifying binding by said antibody. A kit is defined as a set or collection of articles used together therefore Doucette-Stamm et al anticipate a diagnostic kit.

Status of the Claims

6. No claims are allowed.
- Claims 2-10 and 13-17 are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nina A Archie/
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Examiner

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REM 3B31

/Mark Navarro/

Primary Examiner, Art Unit 1645